# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

**CURRENT REPORT** 

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 7, 2023

# **MICROBOT MEDICAL INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 000-19871 (Commission File Number) 94-3078125 (IRS Employer Identification No.)

288 Grove Street, Suite 388 Braintree, MA 02184 (Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (781) 875-3605

#### (Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value	MBOT	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

## Item 8.01 Other Events

On December 7, 2023, Microbot Medical Inc. (the "Company") issued a press release announcing the successful completion of its GLP pivotal pre-clinical study, a critical milestone for the Company's planned IDE submission to the U.S. Food and Drug Administration to commence its human clinical study. The histopathology and lab report supplements previous positive Company findings.

The study was conducted by three leading interventional radiologists that utilized the Company's LIBERTY Endovascular Robotic Surgical System to perform a total of 96 robotic navigations. Target vessels with surrounding tissue were examined and evaluated microscopically after they were subjected to procedures using a range of commercially available intravascular catheterization devices controlled and manipulated via the LIBERTY Endovascular Robotic Surgical System.

The press release, which is filed as Exhibit 99.1 to this Current Report on Form 8-K, is incorporated herein by reference.

## Item 9.01 Financial Statements and Exhibits

Exhibit	Description
99.1	Press release, dated December 7, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

# MICROBOT MEDICAL INC.

By: /s/ Harel Gadot

Name: Harel Gadot Title: Chief Executive Officer, President and Chairman

Date: December 7, 2023



# Microbot Medical Announces the Successful Completion of Its GLP Pivotal Pre-Clinical Study, a Critical Milestone for Its IDE submission to Commence Human Clinical Study

The final histopathology and lab report supplements previous positive Company findings.

The results of the study will support the Company's IDE submission to the FDA to commence its human clinical study

**BRAINTREE, Mass., December 7, 2023** – Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY<sup>®</sup> Endovascular Robotic Surgical System, today announces the successful completion of its GLP pivotal pre-clinical study, done under the guidelines of FDA-required levels of planning, controlling, monitoring, and reporting, using a porcine model.

The study was conducted by three leading interventional radiologists that utilized the LIBERTY Endovascular Robotic Surgical System to perform a total of 96 robotic navigations. Target vessels with surrounding tissue were examined and evaluated microscopically after they were subjected to procedures using a range of commercially available intravascular catheterization devices controlled and manipulated via the LIBERTY Endovascular Robotic Surgical System.

"I am very pleased with the positive outcomes of the histopathology report and the completion of the GLP study," said Juan Diaz Cartelle, Chief Medical Officer. "This gives us confidence to move forward to the next stage of human clinical study."

"Today's announcement marks another important milestone for the Company, as we continue our transition from R&D and pre-clinical phase into the clinical, regulatory and pre-commercial phase" commented Harel Gadot, CEO. "We expect to submit our IDE application to the FDA soon and commence our pivotal human clinical study, completing our transition to a clinically stage company."

#### About Microbot Medical

Microbot Medical Inc. (NASDAQ: MBOT) is a pre-clinical medical device company that specializes in transformational micro-robotic technologies, with the goals of improving clinical outcomes for patients and increasing accessibility through the natural and artificial lumens within the human body.

The LIBERTY<sup>®</sup> Endovascular Robotic Surgical System aims to improve the way surgical robotics are being used in endovascular procedures today, by eliminating the need for large, cumbersome, and expensive capital equipment, while reducing radiation exposure and physician strain. The Company believes the LIBERTY<sup>®</sup> Endovascular Robotic Surgical System's remote operation has the potential to be the first system to democratize endovascular interventional procedures.

Further information about Microbot Medical is available at http://www.microbotmedical.com.

### Safe Harbor

Statements to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for Microbot Medical Inc. and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects" and "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, market conditions, risks inherent in the development and/or commercialization of potential products, including LIBERTY, the outcome of its studies to evaluate LIBERTY technology while it stabilizes its financial condition and seeks additional working capital, any failure or inability to recruit physicians and clinicians to serve as primary investigators to conduct regulatory studies which could adversely affect or delay such studies, uncertainty in the results of pre-clinical and clinical trials or regulatory pathways and regulatory approvals, disruptions resulting from new and ongoing hostilities between Israel and the Palestinians, such as employees of Microbot and its vendors and business partners being called to active military duty, any lingering uncertainty resulting from the COVID-19 pandemic, need and ability to obtain future capital, and maintenance of intellectual property filed with the Securities and Exchange Commission (SEC), which are available on the SEC's web site at www.sec.gov. Microbot Medical disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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